

**“A COMPARATIVE STUDY OF COMBINATION OF  
VAGINAL MISOPROSTOL AND FOLEY BULB  
COMPARED WITH VAGINAL MISOPROSTOL ALONE  
FOR CERVICAL RIPENING AND INDUCTION OF  
LABOR.”**

**Dissertation submitted to**

*In partial fulfilment of the requirements for the degree of*

**M.D BRANCH II**

**OBSTETRICS AND GYNAECOLOGY**



**THANJAVUR MEDICAL COLLEGE**

**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY**

**CHENNAI, TAMILNADU**

**May 2018**

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This is to certify that the dissertation entitled “**A COMPARATIVE STUDY OF COMBINATION OF VAGINAL MISOPROSTOL AND FOLEY BULB COMPARED WITH VAGINAL MISOPROSTOL ALONE FOR CERVICAL RIPENING AND INDUCTION OF LABOR.**” is a bonafide record work done by **Dr. KANDKURTIKAR RACHANA RAMCHANDRA** under my direct supervision and guidance, submitted to the Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of University regulation for M.D Branch II – Obstetrics & Gynaecology.

**Prof. S.PRADEEBA MD,**  
Professor and Head  
Department of Obstetrics and Gynecology,  
Thanjavur medical College  
Thanjavur – 613004

**Prof.Dr.S.Jeyakumar,M.S.,M.Ch.,**  
The Dean  
ThanjavurMedical College  
Thanjavur – 613004



# Thanjavur Medical College

THANJAVUR, TAMILNADU, INDIA - 613001

(Affiliated to the T.N.Dr.MGR Medical University, Chennai)



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submitted by Dr. KANDKURTIKAR RACHANA RAMACHANDRA of

Dept. of OBSTETRICS & GYNAECOLOGY Thanjavur Medical College, Thanjavur

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delivery of the foeto-placental unit it is well recognized that the success of induction of labor which ultimately aims at achieving vaginal delivery depends to a great extent on the favorability of the cervix.

delivery of the fetus It is well recognized that the success of induction of labour, which ultimately aims at achieving vaginal delivery depends to a great extent on the favorability of the cervix

The incidence of labor induction has continued to rise over the past several decades. In developed countries, the number of newborns delivered at term following induction of labor can be as high as one in four deliveries. The World Health Organization Global Survey on Maternal and Perinatal Health, conducted in 24 countries which included nearly 3, 00,000 observations, showed that 9.6% of them were delivered by labor induction

Labor induction in presence of unfavorable cervix is associated with an increased likelihood of prolonged labor and increased incidence of chorioamnionitis and cesarean section; hence the use of cervical ripening agents prior to conventional methods of induction is standard practice

Most commonly used medical agents for cervical ripening are prostaglandins such as Misoprostol. Misoprostol is a less costly, safe synthetic prostaglandin E1 analog and is available as 100 and 200 µg tablets.

## **DECLARATION**

I **Dr. KANDKURTIKAR RACHANA RAMCHANDRA** solemnly declare that the dissertation titled **“A COMPARATIVE STUDY OF COMBINATION OF VAGINAL MISOPROSTOL AND FOLEY BULB COMPARED WITH VAGINAL MISOPROSTOL ALONE FOR CERVICAL RIPENING AND INDUCTION OF LABOR.”** has been prepared by me. I also declare that this bonafide work or a part of this work was not submitted by me or anyother for any award, degree, diploma to any other University board either in India or abroad. This is submitted to The Tamilnadu Dr. M. G. R. Medical University, Chennai in partial fulfilment of the rules and regulation for the award of M.D degree Branch – II (Obstetrics & Gynaecology) to be held in May 2018.

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## ABBREVIATIONS

PG	Prostaglandin
NO	Nitric Oxide
PGE2	Prostaglandin E2
NSAID	Non steroidal Anti inflammatory drug
EASI	Extra-amniotic saline infusion
RMH	Raja Mirasudar Hospital
LSCS	Lower segment Caesaream Section
GDM	Gestatioal Diabetes Mellitus
GHT	Gestational Hypertension
LMP	Last Menstrual Period
EDD	Excepected delivery date
USG	Ultrasonogram
AFI	Amniotic Fluid Index
FHS	Fetal Heart Sound

# INTRODUCTION

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Over the past many years, obstetricians are fascinated with the process of parturition. Thus, the concerns for maternal well-being and timing of birth have been extensively studied to generate many approaches to initiate labor.

Methods such as vaginal or uterine douches, stimulant injections put into the rectum, and the use of ergot alkaloid have been dropped because of their “ineffectiveness or harmful effects on the infant”.

Since antiquity, various methods have been used in attempt to bring on labor.

Induction of labor is a common obstetric procedure; It is defined as the artificial initiation of labor before its spontaneous onset for the purpose of delivery of the feto-placental unit it is well recognized that the success of induction of labor which ultimately aims at achieving vaginal delivery depends to a great extent on the favorability of the cervix.

The incidence of labor induction has continued to rise over the past several decades. In developed countries, the number of newborns delivered at term following induction of labor can be as high as one in four deliveries. The World Health Organization Global Survey on Maternal and Perinatal Health, conducted in 24 countries which included nearly 3, 00,000 observations, showed that 9.6% of them were delivered by labor induction

Labor induction in presence of unfavorable cervix is associated with an increased likelihood of prolonged labor and increased incidence of chorioaminionitis and cesarean section; hence the use of cervical ripening agents prior to conventional methods of induction is standard practice

Most commonly used medical agents for cervical ripening are prostaglandins such as Misoprostol. Misoprostol is a less costly, safe synthetic prostaglandin E1 analog and is available as 100 and 200 µg tablets.

Prostaglandin was first isolated by Vif von Euler from seminal fluid of sheep; it was believed to be part of prostatic secretions hence called prostaglandin.

A Cochrane meta-analysis of trials revealed that vaginal misoprostol improved cervical ripening with an increased rate of vaginal delivery within 24 hours compared with placebo.

A meta-analysis was done by Sanchez-Ramos et.al, who concluded that there was higher rate of tachysystole and uterine hyper stimulation with misoprostol without significant difference in NICU admissions and APGAR score less than 7 at 5 minutes.

### **Foley's catheter induction:**

It is a mechanical method of labor induction. The mechanisms of action for mechanical methods include dilation of the cervix through mechanical pressure and increased prostaglandin production.<sup>23-24</sup> Advantages proposed for these mechanical methods include simplicity of use, potential for reversibility, reduction in certain side effects such as excessive uterine activity, and low cost.<sup>25</sup>

Foley catheters of size 14-26 F with inflation volume of 30-80 ml, and the EASI with infusion rates of 30-40 ml/hour have been shown to be safe and efficacious. A small degree of traction on the catheter by taping it to the inside of the leg<sup>26-27</sup> or infuse extra-amniotic saline through the catheter can be done.<sup>28-30</sup>

Thus although the best agent and method for induction of labor remains uncertain and needs further research, it is biologically plausible that a combination of a mechanical device (Foley's bulb) and chemical agent (misoprostol) may have an additive or synergistic effect, resulting in a greater degree of cervical ripening and shorter induction to delivery time.

The addition of a synthetic prostaglandin to the Foley bulb may also overcome the frequent observation of cervical dilatation with the Foley bulb without significant effacement.

## AIMS AND OBJECTIVES

---

- To test the hypothesis that the use of Foley's bulb plus vaginal Misoprostol will result in shorter induction to delivery time compared with vaginal Misoprostol alone.



## REVIEW OF LITERATURE

### Cervical ripening

---

#### **Cervix:**

Normal anatomy and physiology:

The Two basic parts of uterus are corpus that is uterine body and cervix. Cervix is spindle shaped and measures about 2.5 cm or little more. It opens at each end by small aperture i.e., internal os and external os. The upper segment of cervix that is the portion of cervix that lies above the vaginal attachment is PORTIO SUPRAVAGINALIS. The most caudal part of cervix that is the portion of cervix that protrudes into the vagina is called PORTIO CERVICIS UTERI.

Body of the uterus is mainly composed of smooth muscle cells and extra cellular matrix. Cervix consists mainly of connective tissue. The cellular components of cervix include smooth muscle, fibroblasts and epithelia. Smooth muscle of cervix constitute only 10-15% of tissue,<sup>1</sup> (Dan forth 1983) remaining cellular components contributed mainly by connective tissue (85-90%).

Constituents of extra cellular matrix are mainly collagen bundles, type I, type III and type IV. Water, glycosaminoglycans and proteoglycans are important constituents of extra cellular matrix, especially dermatan sulphate, hyaluronic acid and heparan sulphate. Fibronectin, laminin and elastic fibres are constituents of extra cellular matrix.

In human reproduction cervix plays a dual role as during pregnancy,<sup>2</sup> it remains firm and close and during parturition, it softens and dilates, allowing the fetus to pass through the birth canal.

Cervical ripening is the process by which cervix becomes soft compliant and partially dilated which is thought to be due to combination of biochemical, endocrine, mechanical and possibly inflammatory events.<sup>2</sup>

### **Factors that affect cervical ripening:**

FACTORS	MECHANISM OF ACTION
Change in ground substance(glycosaminoglycans)	Increase in the water content of cervix which causes ‘scattering and dispersion ‘of collagen.  Increased formation of immature collagen.
Enzymes and inflammatory mediators e.g. elastase, collagenase etc	Increased collagen breakdown and remodeling

TABLE NO: 1

Cervix is structurally composed mainly of collagen. There are four types of collagen in human body. There are typeI, II, III and IV. Cervix is predominantly composed of typeI (66%) and type II (33%). Each collagen molecule is composed of three alpha chains which wind around each other to form pro- collagen. Multiple collagens, triple helical molecule are cross linked to one another by action of lysyl oxidase to form long fibrils.

The firmness of cervix is mainly due to properties of these collagen fibrils, which are bound together tightly in the form of bundles<sup>2</sup>. These bundles in turn are embedded in ground substance, consisting of proteoglycans as well as matrix cellular proteins such as thrombospondin. The Interaction of these fibrils determines size, packing and organization. So collagen fibrils are of uniform diameter and are arranged together in a regular and highly organized pattern. Ripening of cervix causes disorganization of these collagen fibrils and increased space between the fibrils.

Matrix metalloproteases, is an enzyme that is capable of degrading the extra cellular matrix proteins.<sup>3</sup> Collagenase, is a member of metallo proteases, which causes degradation of collagen. Changes, that occur in collagen three dimensional structures correlate more with ripening rather than its degradation. During ripening, there is an increased solubility of collagen. Dynamic changes that happen in collagen structure is responsible for remodeling rather than changes in collagen content.

## Proteoglycans<sup>3</sup>

Proteoglycans are made of central core of proteins, which are linked to glycosaminoglycans.

Proteoglycans  $\Longrightarrow$  protein + glycosaminoglycans.

The proteoglycans present in cervix are decorin or biglycan. Hyaluronan is, one of the glycosaminoglycans whose synthesis is up regulated in the cervix during ripening. Function of hyaluronan is mainly dependant on the size. The Changes occurring in proteoglycans composition are associated with cervical ripening. Decorin(a small proteoglycan) interacts with collagen, which in turn influences the packing and arrangement of collagen fibrils<sup>4</sup>. The net result of their decreased expression is rearrangement of collagen, so that collagen fibers are weakened, shortened and disorganized.

### **Glycosaminoglycans:**

These are the repeating disaccharide units, composed of a hexosamine(glucosamine /galactosamine) and an uronic acid (glucouronic acid or iduronic acid) residue. Cervix mainly has glycosaminoglycans that are dematan sulphate and chondroitin sulphate, both of which are highly negatively charged and hydrophobic.

Hence they repel water and are responsible for the firmness of the cervix. Moreover the interaction of glycosaminoglycans with central protein core as well as among them facilitates the optimum orientation of the collagen fibrils enhancing mechanical strength of the cervix.

## Changes responsible for cervical ripening

Dermatan sulphate or chondroitin sulphate (hydrophobic)



Replaced by hyaluronic acid (hydrophilic)



Imbibes water and becomes soft



Destabilises collagen fibrils (decreases mechanical strength)



Cervix becomes soft and compliant i.e., “**cervical ripening**”

In late pregnancy, cervix loses the firmness and becomes soft and compliant. During labor, it further loses its elasticity, viscosity and plasticity. These changes can be attributed to the changes taking place at the molecular level with regard to glycosaminoglycans. Towards term, the concentration of glycosaminoglycans in the cervix alters and dermatan sulphate and chondroitin sulphate are replaced by hyaluronic acid (hydrophilic) and imbibes water. The accumulation of water within the substance of the cervix destabilizes the collagen fibrils, contributing to cervical ripening.

The water content of human cervix is 80% in non pregnant state which increases to 86% in late pregnancy<sup>5</sup> ( Liggins 1978). The effective concentration of collagen in cervix is decreased due to the increased water content and also the effective concentration of collagen in cervix is decreased, though total content of collagen increases at term, further accumulation of water in between collagen fibrils has a scattering or dispersing effect, resulting in reduced mechanical strength.



## **Role of enzymes in cervical ripening: <sup>2</sup>**

- Collagenase is an enzyme which breaks down collagen type I and II. It is produced by fibroblasts and leucocytes.
- Leucocytes elastase is another enzyme that breaks down elastin, collagen and proteoglycans.

It is produced by macrophages, neutrophils and eosinophils. Levels of both of these enzymes found to increase with advancing gestation and are associated with progressive decline in the concentration of cervical collagen.

Parturition is divided into two main phases:

- Conditioning phase i.e. preparatory phase
- Irreversible active labor phase<sup>6</sup> (Chwalisz and Garfield 1997)

Cervical ripening is an integral part of the conditioning phase of parturition and it occurs independently of uterine contraction<sup>7,8</sup> (Lappert 1995; Chwalisz and Garfield 1997). It is an active biochemical process similar to inflammatory reaction, involving infiltration of leucocytes, activation of degradative enzymes (Matrix metalloproteases

and LPS). All these cause rearrangement of extra cellular matrix proteins and glycoproteins.<sup>7,8</sup>

Progesterone plays an important role in cervical ripening, since its anti progestins are effective agents in inducing cervical ripening<sup>7</sup> (chwalisz 1998). Moreover, cervical ripening starts long before decrease in progesterone concentration in the serum occurs, thus indicating additional progesterone independent mechanism.

Oestrogen has also been said to have a role in cervical ripening, as vaginally applied oestrogen has shown to promote cervical ripening.

And also, relaxin and ovarian and placental hormone stimulate cervical ripening.<sup>10</sup> Corticotrophin releasing hormone is considered to play a role in cervical ripening. This hormone is synthesized by placenta and myometrium during pregnancy.<sup>6</sup> It is believed to contribute to the up regulation of inducible nitric oxide synthetase. It stimulates prostaglandin production and is thought to act synergistically with oxytocin during labor.

During Parturition there is increase in different interleukins in the cervix, as well as in the chorio-decidua and the amnion.<sup>11</sup> the levels of interleukin 8 correlate with the expression of the collagenases and

increase at term vaginal delivery. And moreover tumor necrosis factor alpha appears to be involved in cervical ripening.

These inflammatory events result in extravasation of leucocytes and vasodilatation<sup>12</sup> and is considered to be a major source of collagen degrading Matrix metalloproteases, which is capable of degrading collagen as well as other extra cellular matrix components.

Matrix metalloproteases (MMP-8) appears to play a main role in these processes. It has also been suggested that MMP-1 and MMP-3 are involved in cervical ripening process<sup>9</sup>.

**Cyclo-oxygenases:**

Is a rate limiting enzyme in the biosynthesis of prostaglandins. In addition to the well characterized constitutive form of cyclo-oxygenase 1,<sup>13</sup> an inducible form of cyclo-oxygenase 2, is found in the endothelial cells and the macrophages. cyclo-oxygenase 2 is typically undetectable in most tissues under normal physiological conditions, but following stimulation can be expressed at high levels. Recent study has shown that there is increase in cyclo-oxygenase 1 and cyclo-oxygenase 2 at the time of parturition.<sup>14</sup>

In several studies, it has been concluded that prostaglandins stimulate the release of nitric oxide.<sup>15</sup> 15 – OH prostaglandin dehydrogenase, an enzyme that is responsible for the metabolism of prostaglandins to inactive metabolite is lower in the chorion in pre term labor and the activity is decreased by anti progestins and cortisol.<sup>16</sup> Thus decreased activity of 15 – OH prostaglandin dehydrogenase at term plays a role in the process of ripening of cervix.

## **Role of prostaglandins, cyclo-oxygenase and nitric oxide in cervical ripening:**

Prostaglandin especially prostaglandin 2 has for long been thought of as being a key mediator in cervical ripening.<sup>16</sup> It acts by cervical vessel dilation and extravasation of leucocytes.<sup>12</sup> Prostaglandins are synthesized in amnion, deciduas, chorion, myometrium, placenta and cervix.

In human cervix, main prostaglandin synthesized is, prostaglandin E2. Prostaglandin E2 acts mainly as vaso active agent. It principally facilitates inflammatory cell infiltration and regulates the release of cytokines and also stimulates collagenase activity.<sup>17</sup>

the contractile effect of prostaglandin in uterus is well documented but their role in process of ripening of cervix has been questioned. This process of ripening is independent of contraction of uterus.

**Labor induction:**

Induction of labor refers to the artificial stimulation of uterine contractions before the true onset of spontaneous labor in order to achieve vaginal delivery by medical or surgical means.

Augmentation of labor refers to increasing the frequency and the intensity of already existing uterine contractions in a patient in true labor but progressing inadequately, in order to achieve vaginal delivery.

It can also be defined as an intervention designed to artificially initiate uterine contraction, leading to progressive dilatation and effacement of cervix and birth of the infant.<sup>18</sup>

Induction of labor has unwanted effects, but it is indicated when it is agreed that when the fetus or mother benefit from high probability of healthy outcome than if birth is delayed.

It includes both women with spontaneous rupture of membranes who are not in labor and women with membranes intact. Labor induction is considered when vaginal delivery is felt to be appropriate route of delivery.

The incidence of labor induction has been continuously rising over the past several decades.<sup>31</sup> In developed countries, the number of new borns delivered at term following induction of labor can be as high as one in four deliveries.<sup>32</sup> The World Health Organization Global Survey on Maternal and Perinatal Health, conducted in 24 countries which included nearly 3, 00,000 observations, has showed that 9.6% of them were delivered by labor induction.

**Indications and Contraindication:** <sup>22</sup>

<b>Indications for Labor Induction</b>	
<b>Absolute indications</b>	<b>Relative indications</b>
<b>Hypertensive disorders</b>	
Pre-eclampsia/Eclampsia	Chronic hypertension
Postdated pregnancy	Polyhydramnios
Premature rupture of membranes	Fetal anomalies requiring specialized neonatal care
Chorioamnionitis	Psychosocial conditions: Previous precipitate labor, distance from hospital
Intrauterine growth restriction	Previous stillbirth

TABLE NO: 2

<b>Contraindications for Labor Induction</b>	
<b>Absolute indications</b>	<b>Relative indications</b>
<b>Hypertensive disorders</b>	
Vasa previa or complete placenta previa	Malpresentation (breech)
Transverse or oblique fetal lie	Cervical carcinoma
Umbilical cord prolapsed	
Prior classical uterine incision or transfundal uterine surgery	
Absolute cephalopelvic disproportion, contracted pelvis	

TABLE NO: 3

Favourability of cervix is considered as the most important determinant of successful induction of labor.

Favourability of cervix:

Quantifiable method used to predict outcome of induction of labor, score described by bishop.



<b>Criteria for Induction of Labor<sup>22</sup></b>	
<b>Maternal criteria</b>	<b>Fetal criteria</b>
Confirm indication	Confirm gestational age
Rule out contraindications	Assess fetal lung maturity status if required
Perform clinical pelvimetry to rule out cephalopelvic disproportion	Estimate fetal weight (clinically or USG)
Assess cervical condition (Bishop score)	Confirm fetal presentation and lie
Discuss risks and benefits with patient and relatives	Confirm fetal well-being

TABLE NO: 4

## **Bishop score:<sup>19</sup>**

In 1954, Dr. Edward Bishop published his landmark study that developed a critical scoring system. Bishop only advised this scoring system for elective, uncomplicated, multi parous pregnancies. But modern obstetrics practice increasingly uses this scoring system for nulliparous, post dated pregnancy and medical induction of labor.

Tabulating the bishop score requires the assessment of five characteristics<sup>3</sup>

1. Cervical dilatation
2. Effacement
3. Consistency
4. Position
5. Fetal station

Score range: 0-13

Bishop score is one method of assessing the ripeness of cervix.

Bishop scores of 9 or more – likelihood for successful for induction of labor.

Bishop score of 4 or less – identifies an unfavourable cervix considered as indication for cervical ripening.

**Bishop scoring system used for assessment of inducibility.<sup>19</sup>**

Score	Cervical dilatation	Effacement	Consistency	Position	Fetal station
0	Closed	0-30	firm	Posterior	-3
1	1-2	40-50	medium	Mid	-2
2	3-4	60-70	soft	anterior	-1,0
3	>5	>80			+1,+2

TABLE NO: 5

**Cervical effacement:**

Degree of cervical effacement is usually estimated in terms of the length of the cervical canal compared to with that of an uneffaced cervix. If the length of the cervix is reduced by one half, it is 50% effaced. When the cervix becomes as thin as the adjacent lower uterine segment, it is completely or 100% effaced.

**Cervical dilatation:**

It is determined by estimating the average diameter of the cervical opening by sweeping the examining finger from the margin of the cervical opening on one side to that on the opposite side.<sup>3</sup>Diameter transverse is estimated in centimeters. Cervix is said to be fully dilated when the diameter measures 10 cm, because the presenting part of a term sized fetus usually can pass through 10 cm dilated cervix.

**Position of the cervix: <sup>3</sup>**

It is determined by the relationship of cervical os to the fetal head and is categorized as

1. Posterior
2. Mid position
3. Anterior

**Consistency of the cervix: <sup>3</sup>**

It is determined to be

1. Soft
2. Firm
3. Intermediate between these two

## **Level of station of the presenting part of the fetus in birth canal:**

Level of station is described in relation to the ischial spines, which are half way between the pelvis inlet and pelvis outlet.

When the lower portion of the presenting part of the fetus is at the level of the spines, it is designated as being at zero station.

In the past, long axis of the birth canal above and below the ischial spines was arbitrarily divided into thirds by some and into fifths by other groups.

In 1989, American college of obstetrics and gynecologists accepted the classification of station that divides the pelvis above and below the spines into fifths. Each fifth represents a centimeter above or below that spine.

The presenting fetal part descends from the inlet towards the ischial spine; designation is -5, -4, -3, -2, -1 the 0 station.

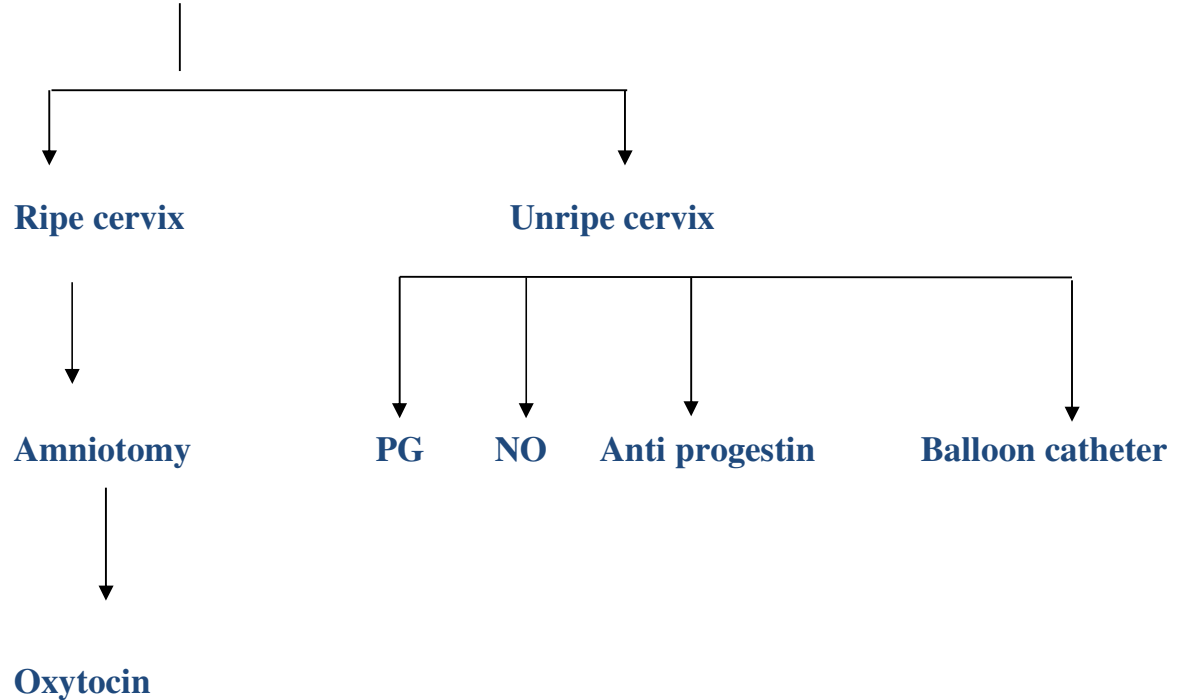
Below the spines, as the presenting fetal part descends, it passes +1, +2, +3, +4 and +5 station to delivery. Station +5 cm represents fetal head is being visible at the outlet.

If the leading part of the fetal head is at 0 station or below, most often the fetal head has engaged thus biparietal diameter has passed through pelvis inlet.

**Different methods of induction according to the intactness  
of membranes and cervical status:**

### **Labor induction**

**Membranes intact**



## **Ruptured membranes**



Women frequently have indication for induction, but with unfavorable cervix. As bishop score favorability decreases there is an increase in chance of unsuccessful induction rate.

Many Researches have been undertaken towards various techniques for cervical ripening prior to induction of labor.



Methods used to improve the favorability of cervix include pharmacological preparation and various mechanical forms.

Optimal method for inducing labor should be efficient but should not cause uterine hyperstimulation. If membranes are ruptured and cervix found to be ripe, method of choice is by stimulation with oxytocin infusion. Oxytocin is administered intravenously as infusion to cause uterine contraction and cervical dilatation.

Action of oxytocin depends on the number of receptors on the uterine myometrial cells than on the actual local hormone concentrations. In case of unripe cervix, both prostaglandins and oxytocin can be used.

If membranes are intact with ripened cervix, labor is most commonly induced with either amniotomy or oxytocin or combination of both. If cervix is unripe, different methods can be used for inducing cervical ripening before onset of contraction.

<b>Methods of Cervical Ripening<sup>22</sup></b>		
<b>Mechanical methods</b>	<b>Surgical methods</b>	<b>Medical methods</b>
Membrane stripping	Amniotomy	Oxytocin
Mechanical dilators		Prostaglandins <ul style="list-style-type: none"> <li>• E2 (Dinoprostone)</li> <li>• E1 (Misoprostol)</li> </ul>
Hygroscopic dilators <ul style="list-style-type: none"> <li>• Laminaria tents</li> <li>• Lamicel</li> </ul>		Progesterone receptor antagonists (Mifepristone)
Foley balloon catheter <ul style="list-style-type: none"> <li>• Without extra amniotic saline infusion</li> <li>• With extraamniotic saline infusion</li> </ul>		Nitric oxide donors

TABLE NO: 6

**Various pharmacological techniques: for cervical ripening:**

PGE<sub>2</sub> (dinoprostone) is commonly used for cervical ripening. It is available in 2.5ml syringe for an intracervical application of 0.5 mg of dinoprostone.

With women in supine position, tip of the pre-filled syringe is placed intracervically and gel is deposited below the internal cervical os. After application, patient should remain reclined for at least 30 minutes. Doses can be repeated 6 hourly with a maximum of 3 doses recommended in 24 hours.

Alternatively 10 mg of dinoprostone vaginal insert 'cervidil' is also approved for ripening of cervix. It is thin flat rectangular polymeric wafer held within a small, white mesh polyester sac. Sac has long attached tail.

Prostaglandins can be administered orally, sublingually, rectally, vaginally or intra cervically.

Insert provides slower release of medication 0.3 mg/ hr than gel foam. It is used as a single dose placed transversely into the posterior vaginal fornix. Lubricant should be used sparingly, if at all with insertion. Excessive lubricant coat can hinder the release of dinoprostone.

**Disadvantages:**

Prostaglandin preparations may cause uterine tachysystole. Because hyperstimulation use fetal compromise when prostaglandin are used with pre existing spontaneous labor.

Prostaglandin agents are contraindicated in asthma, glaucoma or increased intra ocular pressure.

## **Misoprostol**

Misoprostol is an inexpensive synthetic prostaglandin E1 analog marketed for prevention and treatment of NSAID gastric and duodenal ulcers. Many Studies suggest that vaginal Misoprostol is effective as a cervical ripening and labour induction agent. The first study to describe the successful induction of labor in the case of intrauterine fetal demise was published in 1987. Since then, there have been more than 100 randomized trials studying the efficacy and safety of induction in viable term inductions.

Benefits of misoprostol include low cost its stability at room temperature, rapid onset of action, multiple potential routes of administration (oral, buccal, sublingual, vaginal, rectal). These potential benefits make it an attractive alternative to PGE2.

**Vaginal misoprostol:** A Cochrane review has compared the effects of different doses of vaginal misoprostol. Lower doses compared to higher doses were associated with more need for oxytocin augmentation (dose <50 mcg), less uterine hyperstimulation, with and without fetal heart rate changes, and a non-significant trend to fewer admissions to neonatal intensive care unit. The lower dosage regimens

did not show more failures to achieve delivery within 24 hours. Based on the analysis, the Cochrane reviewers have recommended a starting dose of 25 mcg every four hours.

In many countries misoprostol tablets have been administered through different routes (sublingual, oral, vaginal and rectal). Misoprostol is absorbed faster orally than vaginally, with higher peak serum level, but vaginally absorbed serum levels are more prolonged. Its oral use may be convenient, but high doses could cause uterine hyperstimulation and uterine rupture. Vaginal uses of lower doses are associated with less uterine hyperstimulation. Misoprostol is associated with locally mediated effects. The judicious use of misoprostol for obstetric and gynaegological indications, in appropriate clinical settings, hope to reduce maternal mortality.

Based on contemporary evidence, misoprostol is effective in cervical ripening and labor induction, and also in treatment of primary postpartum hemorrhage. In comparison with other conventional agents, it is stable at room temperature, less expensive, and has fewer systemic side effects. In an initial dose of 25 micrograms every four or six hours, vaginal misoprostol is more effective than oral and sublingual misoprostol.

**According to ACOG definitions:<sup>20</sup>**

Uterine tachysystole: is defined as > 6 contractions in a 10 minute period.

Uterine hypertonus: is defined as a single contraction lasting longer than 2 minutes.

Uterine hyperstimulation: is when either condition leads to a non reassuring fetal heart rate pattern.





**Mechanical treatment:**

Intra cervical Foley's catheter to achieve cervical dilatation prior to the induction of labor represents alternative to medical treatment. This technique was described in 1967.<sup>21</sup> Transcervical foley's catheter found to be effective and a safe method for pre induction cervical ripening ('James et al, Levy et al 2004').

The Foley catheter affects cervical ripening in two ways: Gradual dilatation and separation of the deciduas from the amnion stimulating prostaglandin release. Foley catheters of size 14-26 F with inflation volume of 30-80 mL, and the EASI with infusion rates of 30-40 mL/hour have been shown to be safe and efficacious.

The advantages of Foley catheter when compared with prostaglandins include lower cost, stability at room temperature, reduced risk of uterine tachysystole with or without fetal heart rate (FHR) changes, and applicability in an outpatient setting. It seems that higher insufflations volumes (80 mL) may be more efficacious than lower volumes (30 mL).

The concomitant use of oxytocin with Foley catheter does not seem to shorten the duration of labor. The mean induction to delivery time was shorter with the concomitant use of Foley catheter with vaginal misoprostol. There was no increase in labor complications or adverse perinatal outcomes.

A meta-analysis of randomized controlled trial (RCT) concluded that there was no significant difference between Foley catheter balloon and locally applied prostaglandins in cesarean delivery rates. However, use of prostaglandins had shown a significantly increased risk of excessive uterine activity.

A RCT concluded that induction of labor using mechanical methods compared to prostaglandins resulted in similar cesarean section rates along with a lower risk of excessive uterine activity. Mechanical methods compared with oxytocin had lower risk of cesarean section. The Foley catheter can be associated with risks of rupture of membranes, vaginal bleeding in women with a low-lying placenta, febrile morbidity and displacement of the presenting part.

The goal of induction of labor is to achieve vaginal delivery in a safe and timely manner. A number of randomized trials have compared the use of the foley bulb, oxytocin, and misoprostol in various combinations for labor induction and their results are contradictory with regard to delivery time to induction of labor, successful vaginal delivery and labor complications.

Thus although the best agent and method for induction of labor remains uncertain and needs further research, it is biologically plausible that a combination of a mechanical device (Foley's bulb) and chemical agent (misoprostol) may have an additive or synergistic effect, resulting in a greater degree of cervical ripening and shorter induction to delivery time.

The addition of a synthetic prostaglandin to the Foley bulb may also overcome the frequent observation of cervical dilatation with the Foley bulb without significant effacement.

The aim of this study is to test the hypothesis that the use of transcervical Foley's catheter plus vaginal misoprostol will result in shorter induction to delivery time compared with vaginal misoprostol alone.

## **MATERIALS AND METHODS**

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This is a hospital based comparative study done in pregnant mothers (after 34 completed weeks )admitted in the department of Obstetrics and Gynecology R.M.H during October 2015 to march 2016.

After obtaining institutional ethical committee approval, this study was conducted in 200 patients after obtaining informed written consent; patients were randomly allocated to one of the two study groups.

Group 1 Misoprostol alone group

Group 2 combination of Foley bulb with vaginal Misoprostol group

### **INCLUSION CRITERIA:**

1) Women with singleton viable gestation (34 weeks gestation or greater) cephalic presentation fetus, intact membranes and an unfavorable cervix(bishop score 6 or less.), adequate pelvis

## 2) Indications for induction.

- Postdates
- Preeclampsia
- Chronic hypertension
- Gestational hypertension
- Pregestational diabetes
- Gestational diabetes
- Oligohydramnios

Others (abnormal antenatal testing, alloimmunisation with suspected fetal anemia)

## **EXCLUSION CRITERIA:**

1) Foetal malpresentation.

2) Multi foetal gestation.

3) Spontaneous labor (regular uterine contraction with cervical change), more than five uterine contractions in ten minutes.

4) Contraindications to prostaglandins.

5) Category II or greater fetal heart rate tracing.

- 6) Anomaly foetus.
- 7) Foetal demise.
- 8) Previous cesarean other uterine surgeries
- 9) Fetal growth restriction.

Those women, who wished to participate in the study, were examined vaginally for assessment of pelvis, assessment of cervix for consistency, effacement, dilatation, position and station of the presenting part.

Cardiotocography was done to exclude fetal compromise. Ultrasonography was done to measure fetal biometry and liquor status. Maternal pulse blood pressure and fetal heart rate were recorded before treatment and monitored throughout induction and delivery.

Participating women were randomized in two groups:

Group 1 Misoprostol alone.

Group 2 Combination of Foley's bulb with vaginal Misoprostol.

Women in only Misoprostol group received 25 microgram of Misoprostol per vagina every 4 hours. Once the cervix became

favorable or the patient was in active labor Misoprostol administration was discontinued.

Further management of labor was at the discretion of the labor team with expectant management, amniotomy, or intravenous (IV) Oxytocin per protocol. If indicated IV Oxytocin was started per standard protocol after 4 hours from the last Misoprostol dose. Oxytocin was administered as per standard protocol starting at 2 milliunits/min, increasing by 2 milliunits every 20 minutes until a regular uterine contraction occurs.

Women in the combination group received Misoprostol as per standard protocol 25microgram every 4 hourly in addition a Foley bulb was inserted digitally or under direct visualization with the aid of a sterile speculum. The Foley was inserted through the internal cervical os, filled with 60 mL of normal saline, and then pulled snugly against the internal os. The catheter of the Foley bulb was taped to the patient's inner thigh under gentle traction.

When the Foley bulb had fallen out, further management of labor was at the discretion of the labor team and included expectant management, amniotomy, or IV oxytocin. If indicated, IV oxytocin was started per standard protocol after 4 hours from the last misoprostol



dose. Oxytocin was administered as per standard protocol, starting at 2 milliunits /min, increasing by 2 milliunits, every 20 minutes until a regular uterine contractions occurs. Other aspects of labor management were similar for both groups.

Participant data including demographic characteristics, medical and pregnancy history, labor course, and outcomes were collected. Each indication for labor induction was documented.

The primary outcome measured was induction-to delivery time.

The Secondary outcomes measured were

- Mode of delivery
- APGAR score at 1min and 5 min
- NICU admissions
- Change in Bishop's Score

## **OBSERVATIONS AND RESULTS**

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The categorical variables were described with frequencies and percentages while the continuous variables were described by mean and standard deviation. Chi square test is used to find out the Association for categorical variable and student 't' test was used to compare mean difference.

Software used. SPSS version 2.0, and Microsoft excel 2010 to generate graphs.

'P' value  $<0.05$  is significant.

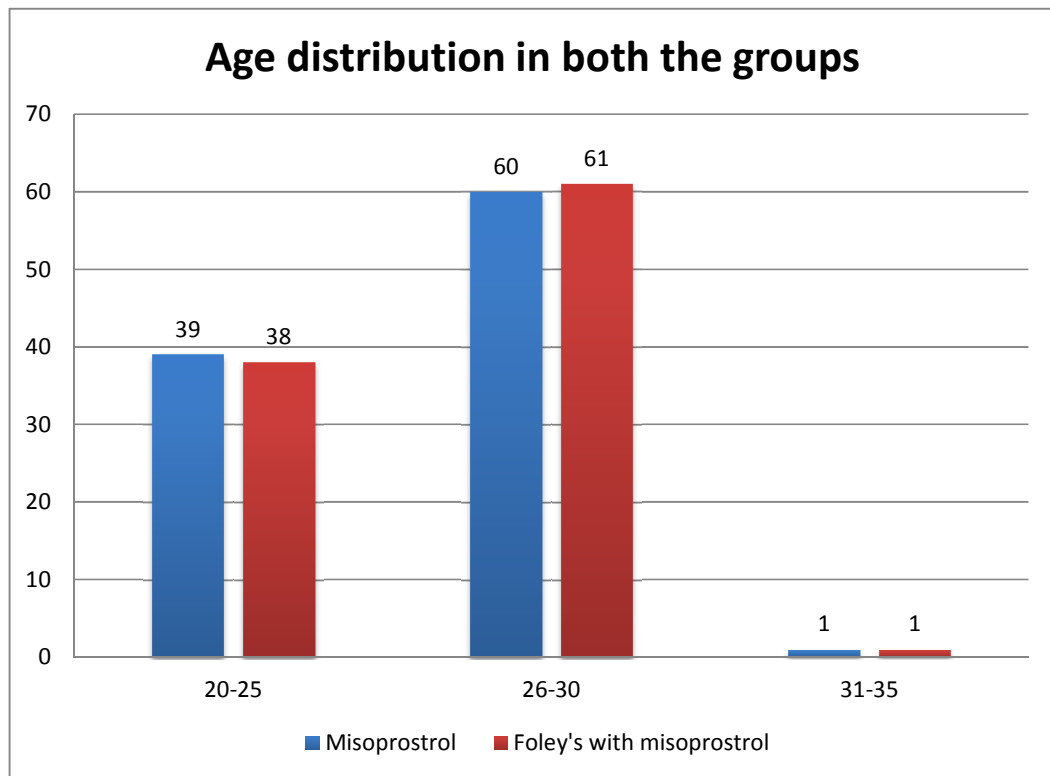
## Results

Our study included a total of 200 patients, consisting of 100 pregnant mothers in Misoprostol alone group and 100 in Foley's catheter plus misoprostol group.

**TABLE NO: 7 Age distribution of combination and Misoprostol alone group**

Group		Frequency	Percent
Misoprostol	20-25	39	39
	26-30	60	60
	31-35	1	1
	Total	100	100
Foley's with Misoprostol	20-25	38	38
	26-30	61	61
	31-35	1	1
	Total	100	100

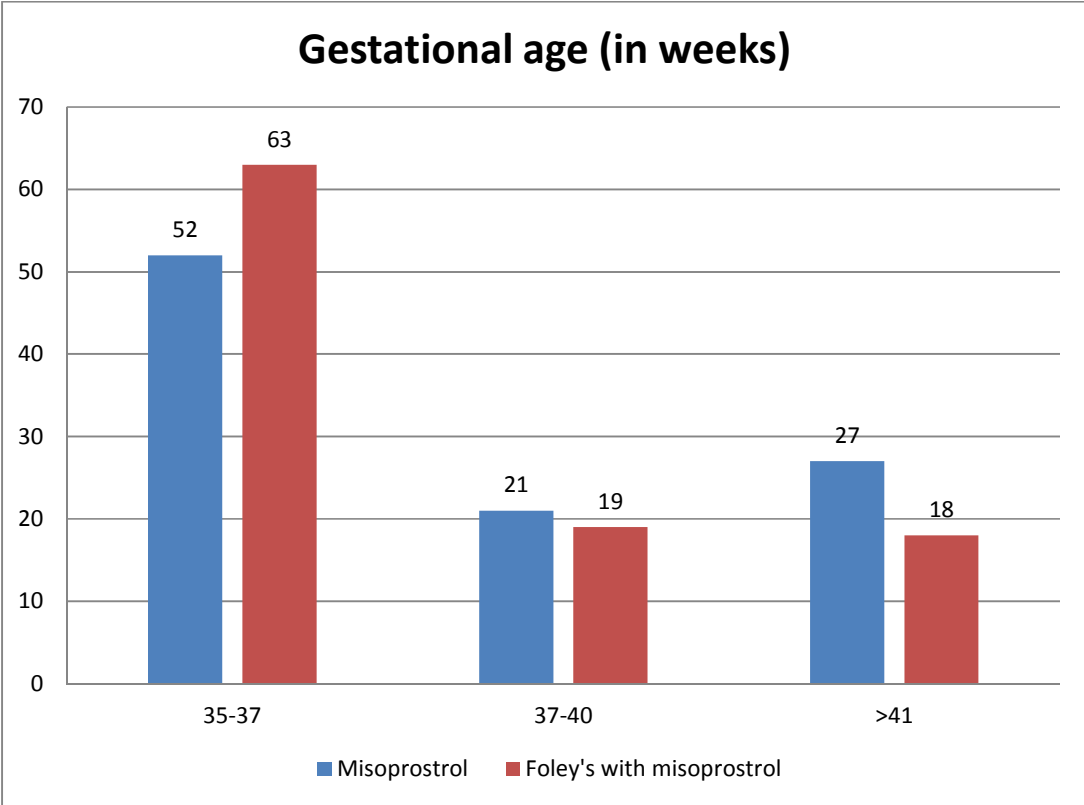
In our study the maximum numbers of pregnant mothers were in the age group of 26 to 30 years in both the groups. In Misoprostol group 60 pregnant mothers from 26 to 30 years and in Foley's plus Misoprostol group 61 pregnant mothers from 26 to 30 years. The mean and the standard variation of age in Misoprostol group and Foley's plus Misoprostol group was  $26.34 \pm 2.19$  and  $26.48 \pm 2.15$ , respectively.



**TABLE NO: 8 GESTATIONAL AGE DISTRIBUTION (In weeks)**

Groups		Frequency		Percent
<b>Misoprostol</b>		<b>35-37</b>	<b>52</b>	<b>52.0</b>
		<b>37-40</b>	<b>21</b>	<b>21.0</b>
		<b>&gt;41</b>	<b>27</b>	<b>27.0</b>
		<b>Total</b>	<b>100</b>	<b>100.0</b>
<b>Foley's with Misoprostol</b>		<b>35-37</b>	<b>63</b>	<b>63.0</b>
		<b>37-40</b>	<b>19</b>	<b>19.0</b>
		<b>&gt;41</b>	<b>18</b>	<b>18.0</b>
		<b>Total</b>	<b>100</b>	<b>100.0</b>

In the study group, the mean and the standard variation of Gestational age, in misoprostol group and Foley catheter plus misoprostol was  $38.10 \pm 2.15$  weeks and  $37.7 \pm 2.00$  weeks, respectively.

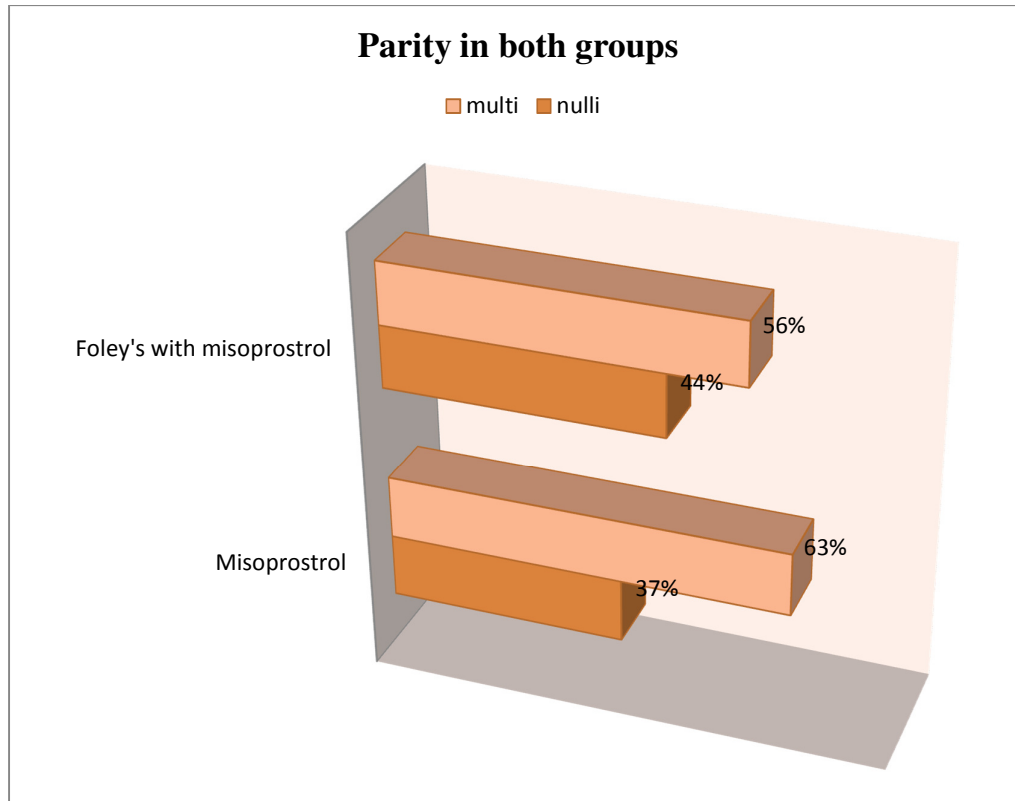


**TABLE NO: 9 Parity in both groups**

		group		Total
		Misoprostol	Foley's with Misoprostol	
Parity	nulliparous	37	44	81
		37.0%	44.0%	40.5%
	multiparous	63	56	119
		63.0%	56.0%	59.5%
Total		100	100	200

OR=0.74(0.42-1.3), CHI SQ=1.017, P=0.388





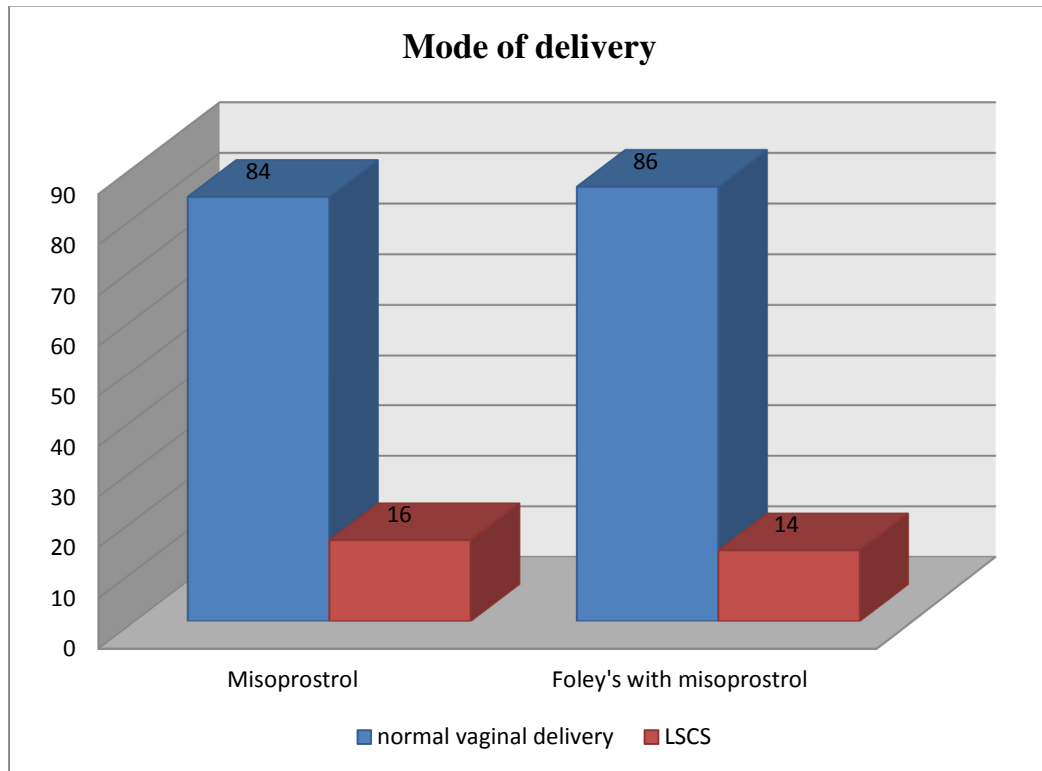
In misoprostol group 37 women were nulliparous and 63 were multiparous and in Foley's plus misoprostol group 44 were nulliparous and 56 were multiparous women. No statistically significant difference in parity between both the groups ( $p = 0.38$ ).

**TABLE NO: 10 Mode of delivery**

			group		Total	
			Misoprostol	Foley's with Misoprostol		
Mode of delivery	NORMAL		84	86	170	
			84.0%	86.0%	85.0%	
	LSCS		16	14	30	
			16.0%	14.0%	15.0%	
Total				100	100	200

Chi sq=0.157, p=0.843, OR=0.855(0.3,1.8)

In misoprostol group, out of 100, 84 delivered normally and 16 patients underwent caesarean section. In combination group 86 patients delivered normally and 14 underwent caesarean section. No statistically significant difference in mode of delivery between both the groups (p = 0.843).

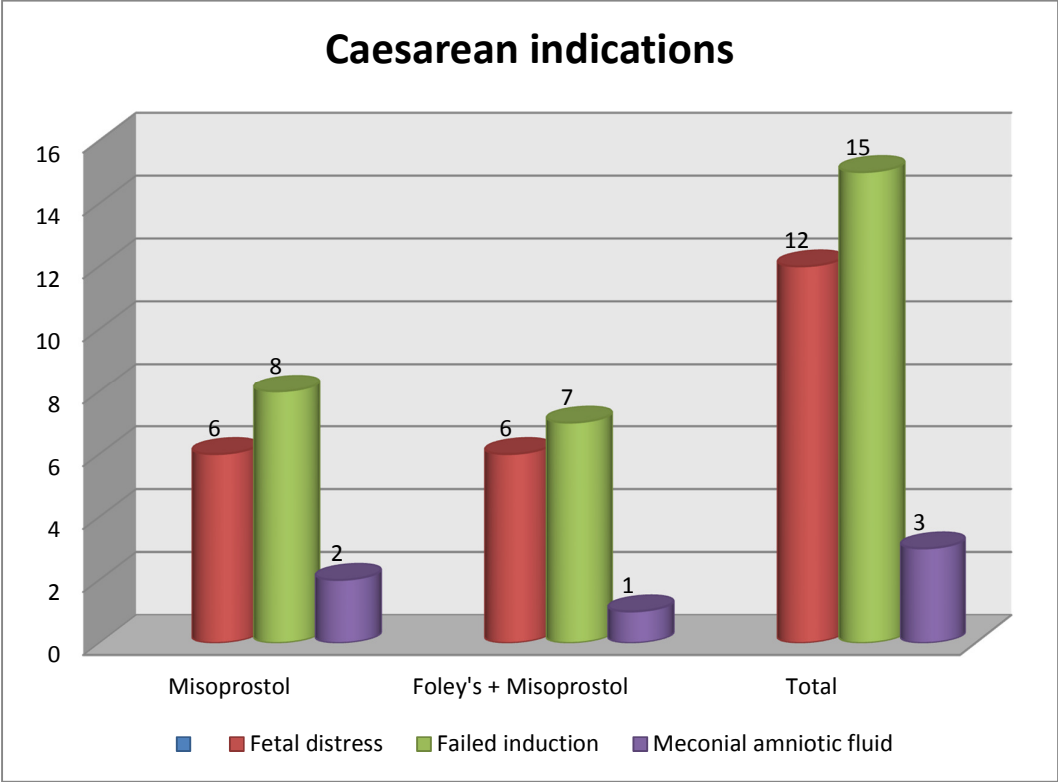


As it is shown in Table no: 10, the rate of vaginal delivery in misoprostol group was 84% and in Foley's plus misoprostol group was 86%. The rate of LSCS was 16% in misoprostol group and 14% in Foley's plus misoprostol group. The calculated p value 0.84 which is insignificant statistically.

**TABLE NO: 11 INDICATIONS OF CAESAREAN SECTION**

	Misoprostol	Foley's + Misoprostol	Total
Cesarean indications	n	n	
Fetal distress	6	6	12
Failed induction	8	7	15
Meconium stained amniotic fluid	2	1	3
Total	16	14	30

In our study the common indications for caesarean section were fetal distress and failed induction. Other indication was meconium stained amniotic fluid.



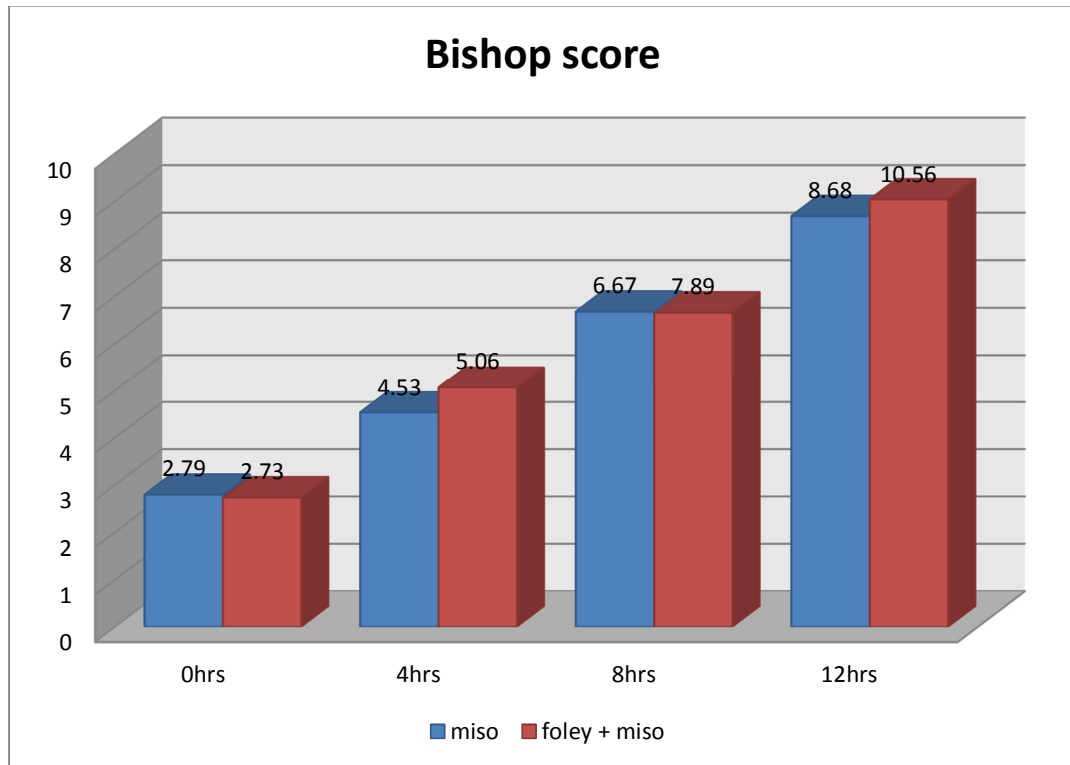
## BISHOP'S SCORE

	Misoprostol group	Foley's + misoprostol group
0hrs	2.79	2.73
4hrs	4.53	5.06
8hrs	6.67	7.89
12hrs	8.68	10.56

**TABLE NO: 12 Bishop's core comparison in both study groups**

In our study Bishop's score at different time intervals in both groups as shown in the above table shows statistically significant p-value ( $< 0.05$ ) at 12 hours time interval.

This shows the faster cervical ripening with Foley's plus vaginal misoprostol group.



Parity	Misoprostol	Foley's + Misoprostol
Nulliparous	8.78	10.27
Multiparous	8.61	10.78

TABLE NO: 13 Comparison of mean of Bishop's score at 12<sup>th</sup> hour in multiparous and nulliparous in both study groups.

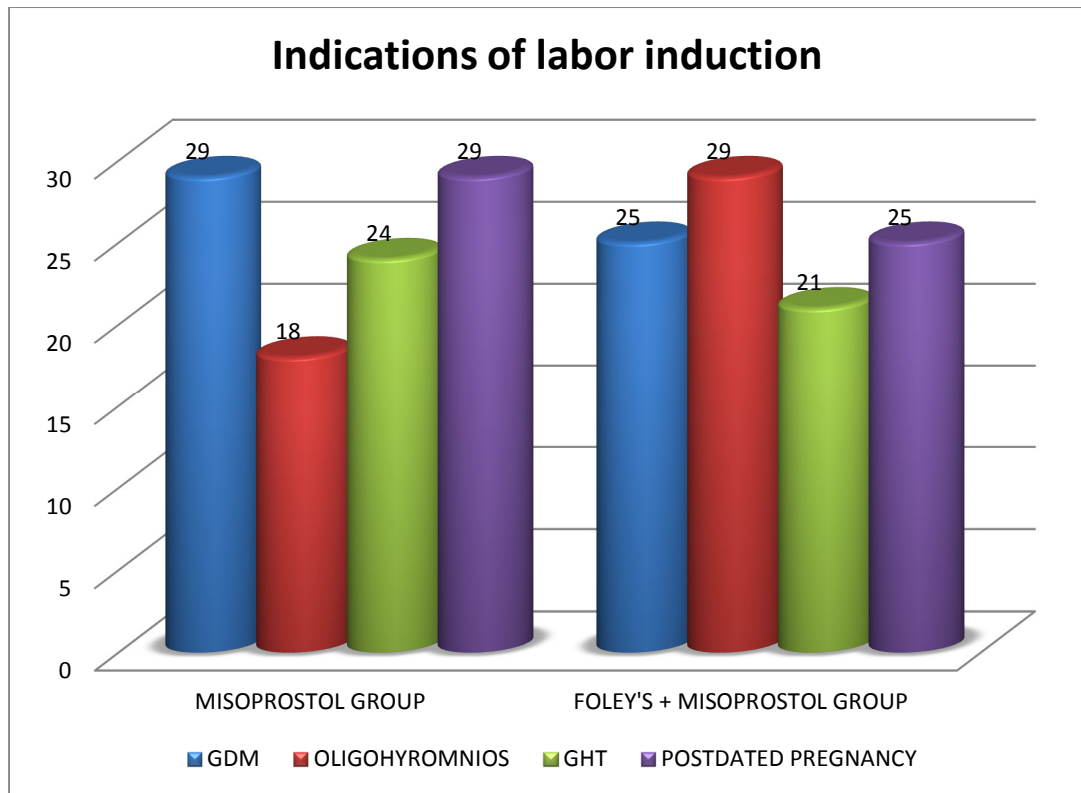
Indications of labor induction		group		Total
		GROUP A	GROUP B	
GDM		29	25	54
		29.0%	25.0%	27.0%
OLIGOHYDRAMNIOS		18	29	47
		18.0%	29.0%	23.5%
GHT		24	21	45
		24.0%	21.0%	22.5%
POSTDATED PREGNANCY		29	25	54
		29.0%	25.0%	27.0%
Total		100	100	200
		100.0%	100.0%	100.0%

TABLE NO: 14

Chi sq=3.36, p=0.33

P value >0.05 statistically not significant





In the present study the most common indication for induction of labor is Oligohydramnios in Foley's plus vaginal misoprostol group and in misoprostol group is Gestational diabetes mellitus and postdated pregnancy.

### Induction to Delivery time

Group		N	Mean	Std. Deviation	P value
Induction To delivery time	Misoprostol	100	14.68	2.20	<0.05
	Foley's with Misoprostol	100	12.71	1.03	

TABLE NO: 15

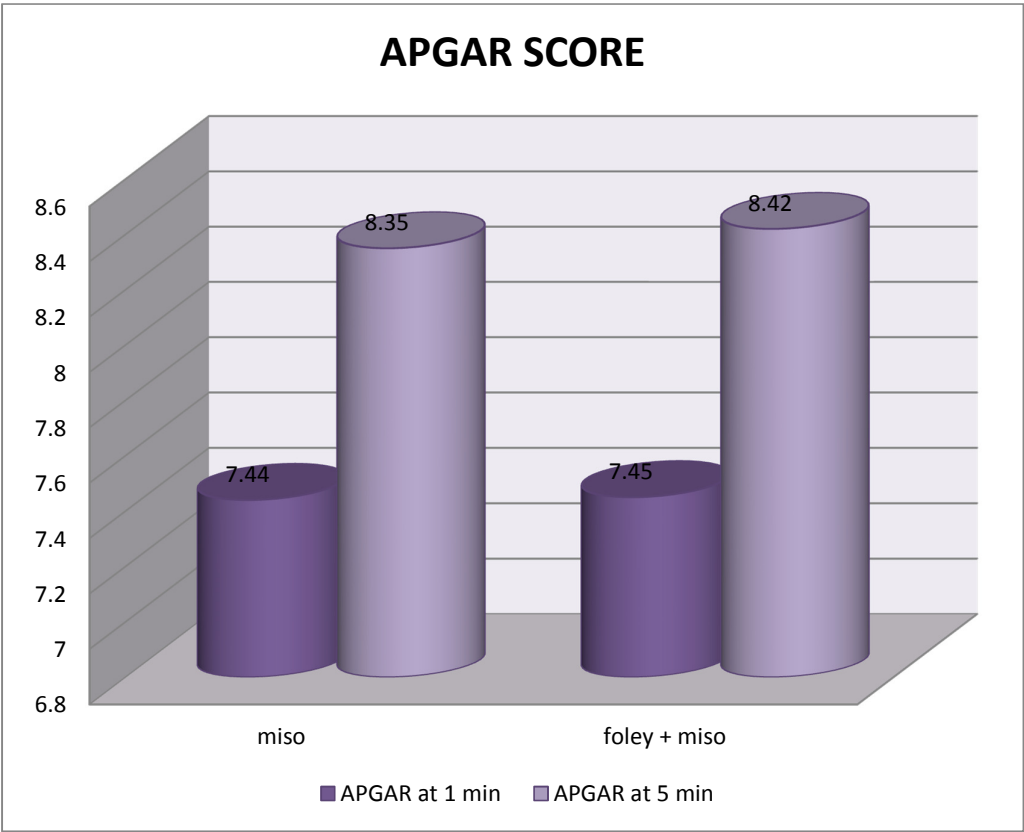
The mean induction to delivery time for combination group is shorter (12.71) than Misoprostol alone group (14.68). 'p' value <0.05 statistically significant

## APGAR SCORE

	Misoprostol group	foley + misoprostol group
APGAR at 1 min	7.44	7.45
APGAR at 5 min	8.35	8.42

**TABLE NO: 16**

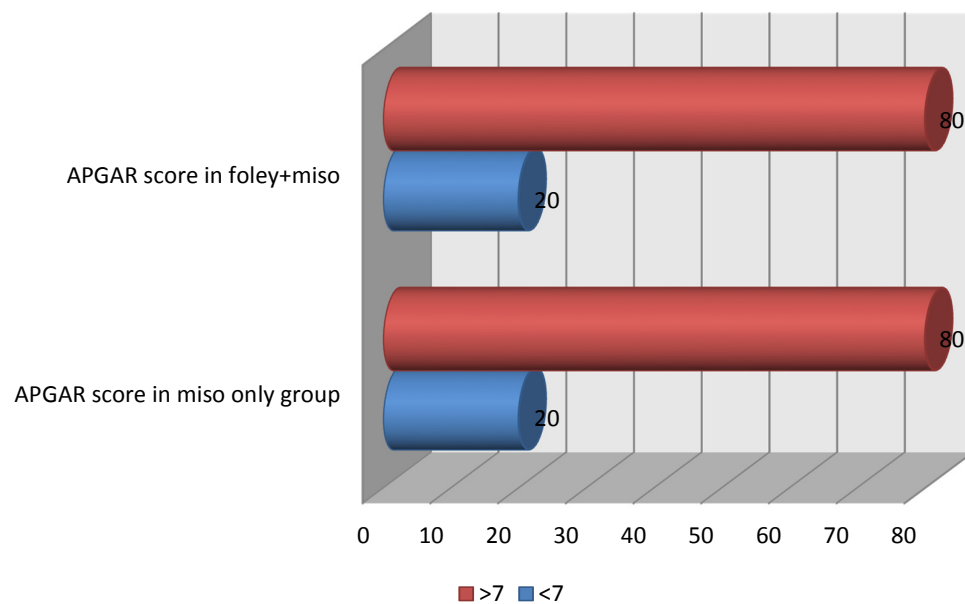
In the present research study statistics for APGAR SCORE done or time interval was p-value 0.95 for the 1<sup>st</sup> minute and p-value 0.55 for the 5<sup>th</sup> minute, which is statistically insignificant.



APGAR SCORE AT 1MIN IN BOTH GROUPS		
	APGAR score in misoprostol only group	APGAR score in Foley + misoprostol group
<7	20	20
>7	80	80

TABLE NO: 17

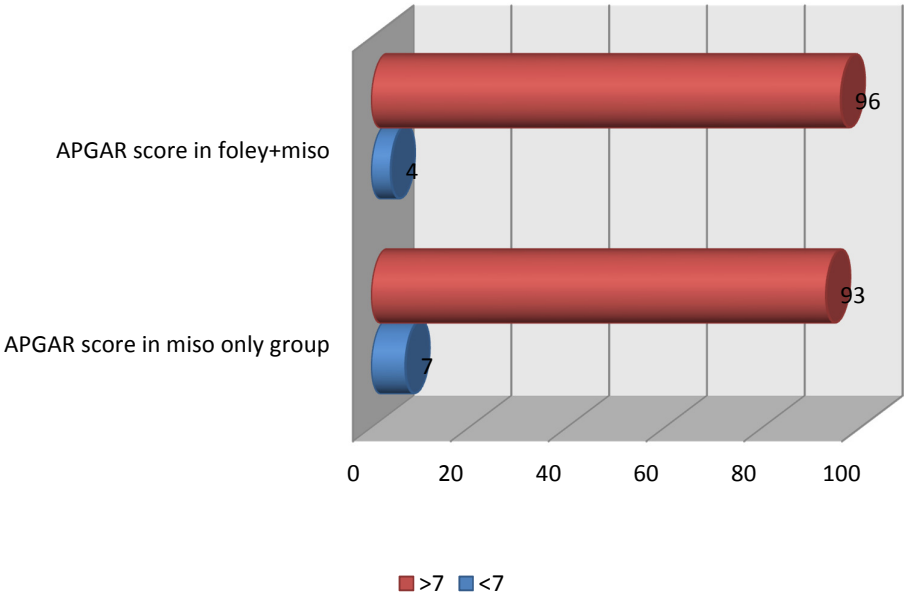
### APGAR SCORE AT 1 MIN



APGAR SCORE AT 5MIN IN BOTH GROUPS		
	APGAR score in misoprostol only group	APGAR score in Foley + misoprostol group
<7	7	4
>7	93	96

TABLE NO:18

**APGAR SCORE AT 5 MIN**





## DISCUSSION

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In this study population, a total of 200 pregnant women (after 34 completed weeks) admitted in the department of Obstetrics and Gynecology R.M.H during October 2015 to march 2016, were enrolled in the study. They were divided into two groups: 100 cases in Misoprostol group as first group and 100 cases in Foley's catheter plus Misoprostol group as second group.

The mean and the standard variation of age in Misoprostol group and combination group (foley bulb + Misoprostol) was  $24.3 \pm 4.0$  and  $24.2 \pm 5.0$  ( $p > 0.1$ ), respectively. Gestational age, Misoprostol group was  $39.8 \pm 1.4$  weeks and in combination group was  $40 \pm 0.9$  weeks ( $p > 0.1$ ).

In this study, two methods of cervical ripening and labor induction with vaginal Misoprostol alone and Foley's catheter plus vaginal Misoprostol were compared. The results of the present study show that the rate of success (i.e. the mean induction to delivery interval was significantly shorter) in Foley's catheter plus vaginal Misoprostol group was more than Misoprostol alone group (p-value

<0.05) with two hours duration. In Hussein et al study nulliparous women of combination group had lower induction to active phase of interval than misoprostol group ( $p=0.003$ )<sup>41</sup>. This showed that the combination of foley's bulb and vaginal misoprostol results in early start of active phase of labour in nulliparous women. It was  $7.45 \pm 4.68$  hours in parous women of combination group and  $6.70 \pm 3.85$  hours in misoprostol group; difference was statistically insignificant ( $p=0.680$ ). Induction to delivery interval was  $11.76 \pm 5.89$  hours in combination group and  $14.54 \pm 7.32$  hours in misoprostol group with difference of 2.78 hours and the difference was statistically significant. In Carbone et al study it was  $15.3 \pm 6.5$  hours in combination group and  $18.3 \pm 8.7$  hours in misoprostol group, difference was of 3.1 hours ( $p=0.03$ )<sup>42</sup>. Olusol.p et.al has studied 210 women with singleton pregnancy. In their study women with Foley's catheter plus vaginal misoprostol for preinduction have showed significant shorter duration of time in cervical ripening time and induction to delivery time<sup>33</sup>.

E.O.Ugwu. et.al conducted a randomized controlled trial over a 14-month period in a tertiary health institution in Nigeria, in three groups i.e. Group A, transcervical Foley's catheter was used synchronously with low dose intravaginal misoprostol; Group B,

transcervical Foley catheter alone was used and Group C, low dose intravaginal misoprostol alone was used to determine the effectiveness for pre-labor cervical ripening. In their study the combination of Foley's catheter and misoprostol is very effective in cervical ripening and concluded that the combination group should be considered in clinical situations where there is need to hasten vaginal delivery in the presence of an unripe cervix.<sup>34</sup>

Sciscione AC et.al compared the efficacy of intravaginal misoprostol with transcervical Foley's catheter for preinduction cervical ripening and concluded that intravaginal misoprostol alone and transcervical Foley catheter are equivalent for cervical ripening. Uterine contractile abnormalities and meconium passage are more common with misoprostol<sup>36</sup>.

Hill JB et.al have compared labor induced by vaginal misoprostol versus a supracervical Foley catheter and oral misoprostol in singleton pregnancies at  $\geq 24$  weeks' gestation. One hundred and twenty-six women were randomized to vaginal misoprostol alone and one hundred and six women to Foley's catheter and oral misoprostol. In their study the time from induction to delivery in group Foley's catheter and

oral misoprostol (12.9 hours) was significantly shorter than that in group vaginal misoprostol (17.8 hours,  $P < 0.001$ )<sup>37</sup>.

In our research study the rate of vaginal delivery in misoprostol group was 84% and in Foley's plus misoprostol group was 86%. The rate of LSCS was 16% in misoprostol group and 14% in Foley's plus misoprostol group. The calculated p value is statistically insignificant. Many other studies also show no much difference and statistically insignificant in rate of vaginal delivery.

In the present study Bishop's score calculated for pregnant women with unfavourable cervixes (Bishop's score  $< 6$ ) requiring cervical ripening/induction of labor has showed statistically significant p-value ( $< 0.05$ ) at 12 hours time interval. A.T.Owalabi et.al studied total of 120 pregnant mothers requiring induction of labor with an unfavourable cervix with receiving either 50  $\mu\text{g}$  intravaginal misoprostol every 6 h for a maximum of two doses, or an intracervical Foley balloon catheter for 12 h followed by an intravenous oxytocin infusion, had showed significant change in the Bishop's score in the two groups ( $5.9 \pm 0.2$  and  $4.0 \pm 0.2$ , respectively,  $p < 0.001$ )<sup>35</sup>.

In our study APGAR scores had done at different time interval showed statistically insignificant p-value 0.95 for the 1<sup>st</sup> minute and p-value 0.55 for the 5<sup>th</sup> minute in both study groups. A.T.Owalabi et.al studied total of 120 pregnant mothers requiring induction of labor with an unfavourable cervix with receiving either 50 µg intravaginal misoprostol every 6 h for a maximum of two doses, or an intracervical Foley balloon catheter for 12 h followed by an intravenous oxytocin infusion, had showed no differences between groups for meconium passage, 1- or 5-min Apgar scores <7 and admission into the neonatal intensive care unit<sup>35</sup>.

Naseer noor et.al studied one hundred and four women with term gestation, with Bishop Score < 4, and with various indications for labor induction, also stated statistically there was no significant difference in the APGAR score between the two groups at 1 minute and 5 minutes<sup>38</sup>. Similar results were found by Filho et al and Roudsari et al and our present study supports these results<sup>39,40</sup>.

## SUMMARY

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- In the present study 200 pregnant mothers (after 34 completed weeks) were studied. In that 100 were in Foley's with vaginal misoprostol group and 100 in vaginal misoprostol alone group.
- In our study the maximum numbers of pregnant mothers were in the age group of 26 to 30 years in both the groups. In misoprostol group 60 pregnant mothers from 26 to 30 years and in Foley's plus misoprostol group 61 pregnant mothers from 26 to 30 years.
- In the study groups, the mean and the standard deviation of Gestational age, in misoprostol group and Foley catheter plus misoprostol was  $38.10 \pm 2.15$  and  $37.7 \pm 2.00$ , respectively.
- In misoprostol group 37 women were nulliparous and 63 were multiparous and in Foley's plus misoprostol group 44 were nulliparous and 56 were multiparous women. No statistically significant difference in parity between both the groups ( $p = 0.38$ ).

- The rate of vaginal delivery in misoprostol group was 84% and in Foley's plus misoprostol group was 86%. The rate of LSCS was 16% in misoprostol group and 14% in Foley's plus misoprostol group. The calculated p value 0.84 which is insignificant statistically.
- In the present research study there was statistically significant difference in Bishop's score, the p-value was <0.05. The mean Bishop's score for vaginal misoprostol alone and Foley's plus vaginal misoprostol was 8.68 and 10.56 respectively.
- In the study among 200 pregnant mothers (after completion of 34 weeks) the indication for induction of labor are GDM, Oligohydromnios, GHT, Post dated pregnancy.
- The mean induction to delivery time for Foley's with misoprostol group is shorter (12.71) than Misoprostol alone group (14.68). With statistically significant p-value <0.05.
- In our study APGAR scores done at different time interval showed statistically insignificant p-value 0.95 for the 1<sup>st</sup> minute and p-value 0.55 for the 5<sup>th</sup> minute in both study groups.
- There were no admissions of neonates in the NICU in both the study groups.

## CONCLUSION

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The results of this comparative study showed that the use of Foley's with vaginal misoprostol results in a shorter induction to delivery time compared with vaginal misoprostol alone.

These results also suggest that the combination of Foley's with vaginal misoprostol may be useful to achieve timely and safe delivery in the presence of unripe cervix.

There were no increased maternal and fetal complications of misoprostol as compared to Foley with misoprostol.

There was significant difference in the improvement in Bishops score between the two groups 12 hours after induction.

There was no statistically significant difference in the mode of delivery between the two groups.

There was no statistically significant difference in the APGAR scores in both the groups.



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# PROFORMA

THANJAVUR MEDICAL COLLEGE, THANJAVUR

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Name:

Age:

IP No:

Unit:

Booking status:

Date of

admission:

H/O Amenorrhoea \_\_\_\_\_ months

Obstetric history:

Present pregnancy:

1<sup>st</sup> trimester:

2<sup>nd</sup> trimester:

3<sup>rd</sup> trimester:

Menstrual history:

Age of menarche:                      previous cycle:  
regular/irregular

LMP:                                      EDD:

USG:

Gestational Age:

Marital History:                      Consanguinity:  
(yes/no)

Past history:

Family history:

Personal history:

General physical examination

Height:              weight:              PR:              BP:

Anaemia:              Icterus:              Cyanosis:              Pedal edema:

CVS:                                      RS:

Examination of abdomen:

Fundal height:

Lie:

Presentation:

Position:

FHS:

Per Vaginal Examination:

Characteristics	Before drug	After drug
1.Dilation		
2.Effacement		
3.Consistency		
4.Position		
5.Fetal station		

Score:

INVESTIGATIONS:

Hb%:

BT:

CT:

Blood Grouping:

Urine

albumin:

sugar:

USG:

AFI:

Consent:

Informed Verbal:

Written Consent:

CARDIOTOCOGRAPHY:

CTG MISOPROSTOL GP	CTG MISOPROSTOL+ FOLEY'S

Nature of labor:

1. Oxytocin Augmentation:
2. Rupture of membranes
3. Color of liquor:
4. Duration of labor
  - I<sup>st</sup> stage
  - II<sup>nd</sup> stage
  - II<sup>rd</sup> stage
5. Mode of delivery:

Vaginal delivery:

LSCS:

Indication

## BABY DETAILS

1. Sex:

2. Birth weight:

3. APGAR SCORE: 1 minute:

5 minute:

4. NICU Admission:

## CONSENT FORM

I \_\_\_\_\_ hereby give consent to participate in the study conducted by **DR KANDKURTIKAR RACHANA RAMCHANDRA** post graduate in department of Obstetrics and Gynaecology, Thanjavur medical college & hospital, Thanjavur – 613001 and to use my personal clinical data and result of investigation for the purpose of analysis and to study the nature of disease. I also give consent for further investigations

Place :

Date :

Signature of participant

# MASTER CHART

## KEY FOR MASTER CART

S. No	Serial Number
B.S	Bishop's score at 12 <sup>t</sup> minute
I O L	Induction of labor
I 2 D T	Induction to delivery time
I 2 C D	Induction to complete dilatation
M.O.D	Mode of delivery
Nulli	nulliparous
Multi	multiparous
wks	weeks
h	hours
y	years
v	Vaginal delivery
c	Cesarean section
msaf	Meconial amiontic fluid
GHT	Gestational hypertension
GDM	Gestational diabetes mellitus
PDP	Post-dated pregnancy
OLIGO	Oligohydramnios

## MASTER CHART FOR MISOPROSTOL GROUP

S.no	Age	Gestational age	Parity	B S	I O L	I 2 DT(h)	I 2 C D(h)	M O D	LSCS ind
1	24y	37wks	nulli	8	GHT	15	12	V	
2	26y	36wks	multi	8	GDM	13	11.3	V	
3	28y	41wks	multi	9	PDP	18	14	V	
4	28y	41wks+2days	multi	9	PDP	16	14.3	V	
5	27y	37wks	multi	8	OLIGO	15	11	V	
6	25y	37wks	nulli	8	OLIGO	14	–	c	msaf
7	26y	36wks	multi	7	GHT	16	10	V	
8	29y	37wks	multi	8	OLIGO	15	10	V	
9	30y	41	multi	8	PDP	19	11.3	V	
10	22y	38wks	nulli	9	GHT	14	10.3	V	
11	26y	37wks	nulli	8	OLIGO	14	12.3	V	
12	25y	36wks	nulli	9	GHT	15	–	c	Failed induction
13	24y	37wks	nulli	7	GHT	13	11.3	V	
14	24y	36wks	nulli	9	OLIGO	14	11.3	V	
15	30y	41	multi	8	PDP	19	12.3	V	



16	26y	36wks	multi	10	GDM	13	–	c	Failed induction
17	23y	38wks	nulli	9	GHT	13	12.3	V	
18	26y	37wks	multi	8	OLIGO	15	12	V	
19	25y	37wks	nulli	9	GDM	12	11.3	V	
20	24y	38wks	nulli	10	OLIGO	14.3	13	V	
21	25y	36wks	multi	8	GDM	12	9.3	V	
22	26y	36wks+5days	multi	8	GDM	13	10	V	
23	30y	37wks	multi	8	OLIGO	14	10	V	
24	29y	41wks	multi	8	PDP	16	14.3	V	
25	28y	35wks+3days	multi	8	GDM	14.3	12	V	
26	25y	36wks+5days	nulli	9	GHT	13.3	12	V	
27	26y	36wks	multi	9	GDM	13	11.3	V	
28	24y	35wks+5days	nulli	10	OLIGO	14	–	c	fetal distress
29	30y	41wks	multi	10	PDP	15	11.3	V	
30	29y	41wks+2days	multi	7	PDP	17.3	10.3	V	
31	24y	37wks	nulli	8	GHT	12	–	c	fetal distress
32	30y	35wks	multi	9	GDM	14.3	12.3	V	
33	25y	39wks	nulli	8	OLIGO	13.5	11.3	V	

34	23y	38wks	nulli	9	OLIGO	14	–	c	msaf
35	25y	41wks	nulli	9	PDP	13.3	11	V	
36	26y	41wks+2days	multi	9	PDP	17	11.3	V	
37	28y	42wks	multi	10	PDP	17.3	11.15	V	
38	29y	38wks	multi	9	GHT	12.3	10.3	V	
39	26y	39wks	multi	8	OLIGO	13.3	11.3	V	
40	25y	35wks+4days	nulli	9	GDM	12.3	11	V	
41	26y	41wks	multi	8	PDP	19	12	V	
42	30y	41wks+3days	multi	9	PDP	20	12.3	V	
43	29y	36wks	multi	8	GDM	14.3	–	c	fetal distress
44	28y	36wks+5days	multi	9	GDM	15	13.3	V	
45	24y	37wks+4days	nulli	9	GHT	13	11	V	
46	25y	37wks	nulli	9	OLIGO	14	10	V	
47	31y	41wks	multi	10	PDP	18.3	11.3	V	
48	24y	35wks	nulli	8	GDM	13.3	–	c	Failed induction
49	25y	36wks	nulli	9	GDM	12.3	11	V	
50	25y	37wks+2days	multi	8	GHT	14	12.3	V	
51	26y	35wks	multi	9	GDM	12	–	c	Failed induction

52	29y	42wks	multi	10	PDP	16.3	13.3	V	
53	28y	41wks+5days	multi	9	PDP	15.3	13.3	V	
54	28y	37wks	multi	11	GDM	13.3	12.3	V	
55	28y	37wks	nulli	10	OLIGO	13	–	c	Fetal distress
56	25y	38wks	multi	9	GHT	12.3	12	V	
57	29y	41wks	multi	8	PDP	17	11	V	
58	28y	41days+2days	multi	11	PDP	19	11	V	
59	26y	40wks+3days	multi	9	PDP	15.3	13.3	V	
60	24y	36wks	multi	9	GDM	12	–	c	Failed induction
61	26y	37wks	multi	7	OLIGO	16	15	V	
62	26y	36wks+3days	multi	11	GDM	11.3	10	V	
63	26y	37wks	multi	12	GDM	14.3	12	V	
64	25y	42wks	nulli	8	PDP	18.3	12	V	
65	29y	35wks+5days	multi	9	GDM	12	11	V	
66	29y	36wks	multi	9	GDM	12.3	11	V	
67	24y	37wks	nulli	8	GHT	15	–	c	Failed induction
68	26y	36wks	nulli	11	GDM	13.3	11.3	V	
69	27y	36wks+5days	multi	8	GDM	12	11	V	

70	27y	42wks	multi	9	PDP	17	–	c	Failed induction
71	26y	39wks	nulli	8	GHT	15	12	V	
72	25y	36wks	multi	8	GDM	13	10	V	
73	25y	35wks	multi	7	GDM	14	11.3	V	
74	24y	37wks	multi	8	GHT	13	10	V	
75	26y	41wks	multi	8	PDP	20	–	c	Failed induction
76	23y	41wks	nulli	8	PDP	16	13.3	V	
77	27y	37wks	multi	7	GHT	13	12.3	V	
78	27y	37wks	multi	9	GHT	13.3	11.3	V	
79	22y	37wks	nulli	11	GHT	12	–	c	fetal distress
80	22y	38wks	nulli	9	OLIGO	14	10	V	
81	29y	41wks	multi	8	PDP	15	12	V	
82	28y	41wks	multi	11	PDP	18	11	V	
83	28y	38wks+5days	multi	10	GHT	14	10.15	V	
84	27y	38wks+6days	multi	8	GDM	11.3	10.3	V	
85	27y	39wks	multi	7	OLIGO	14	11	V	
86	26y	37wks	multi	9	GDM	12	10	V	
87	23y	38wks	nulli	10	GHT	15	10	V	

88	25y	38wks	nulli	9	GHT	19	15	V	
89	24y	38wks	nulli	7	GDM	14.3	12.3	V	
90	30y	41wks	multi	8	PDP	18	12	V	
91	29y	41wks	multi	9	PDP	18	13	V	
92	26y	39wks	nulli	9	GDM	13	10.3	V	
93	27y	39wks+4days	multi	8	GHT	13.3	12	V	
94	24y	42wks	nulli	9	PDP	18.3	12	V	
95	23y	37wk	nulli	7	GHT	14	12.3	V	
96	25y	38wks	multi	6	GHT	14.3	13	V	
97	29y	41wks	multi	8	PDP	19	10.15	V	
98	24y	37wks	nulli	9	OLIGO	15	12	V	
99	30y	40wks+6days	multi	8	PDP	18	10.15	V	
100	29y	37wks	nulli	9	GDM	13	–	c	fetal distress

## MASTER CART FOR FOLEY'S + MISOPROSTOL GROUP

S.no	Age	Gestational age	Parity	B.S	I O L	I 2 D T(h)	I 2 C D(h)	M.O.D	LSCS ind
1	22y	37wks	nulli	11	GHT	13	12	V	
2	22y	36wks	nulli	12	GDM	12	11	V	
3	23y	37wks	Multi	11	GHT	13	12.30	V	
4	23y	37wks+4days	Nulli	7	GHT	14	–	c	fetal distress
5	23y	37wks	Nulli	12	OLIGO	13	11	V	
6	23y	37wks	Nulli	12	OLIGO	13	12	V	
7	23y	36wks	Nulli	11	GHT	12	10.30	V	
8	24y	37wks	Multi	12	OLIGO	12	9.30	V	
9	24y	36wks	Nulli	10	GDM	12	10	V	
10	24y	35wks	Multi	11	GDM	11	9.30	V	
11	24y	35wks+5days	Nulli	8	GDM	13.30	–	c	Failed induction
12	24y	36wks+5days	Nulli	10	GDM	14	13	V	
13	24y	37wks	Nulli	11	GHT	13.30	12	V	
14	24y	37wks	Nulli	12	OLIGO	13.30	12.45	V	
15	24y	36wks	Multi	12	GDM	11	10	V	

16	24y	38wks+5days	Nulli	12	GHT	11.5	9	V	
17	24y	38wks	Nulli	12	GHT	12	10	V	
18	24y	37wjs	Nulli	11	OLIGO	13	12	V	
19	24y	36wks	Nulli	12	OLIGO	12	10.30	V	
20	25y	37wks	Nulli	12	OLIGO	14.30	13	V	
21	25y	36wks	Multi	11	GDM	13.30	12.30	V	
22	25y	36wks	Nulli	8	GDM	15	–	c	Failed induction
23	25y	37wks	Multi	11	OLIGO	12.30	11	V	
24	25y	36wks+5days	Nulli	12	OLIGO	13	12	V	
25	25y	36wks	Multi	12	GDM	12.30	11.30	V	
26	25y	37wks	Nulli	12	OLIGO	13.30	11	V	
27	25y	36wks	Nulli	11	GDM	13	11.30	V	
28	25y	38wks	Nulli	10	OLIGO	12.30	11.30	V	
29	25y	36wks	Multi	12	GDM	11.30	10.30	V	
30	25y	37wks	Nulli	11	GDM	11	10.30	V	
31	25y	37wks	Multi	11	OLIGO	14	13.30	V	
32	25y	36wks+3days	Nulli	8	GDM	14.30	–	c	Failed induction
33	25y	38wks	Nulli	11	OLIGO	13.50	13	V	

34	25y	36wks	Multi	10	GDM	12.30	11.30	V	
35	25y	38wks	Nulli	7	GHT	13.30	–	c	Fetal distress
36	25y	37wks	Nulli	10	GHT	12.30	11	V	
37	25y	37wks	Nulli	9	OLIGO	13	12	V	
38	25y	36wks	Multi	11	GDM	11.30	10.30	V	
39	26y	36wks	Nulli	8	GDM	13.30	–	c	fetal distress
40	26y	37wks	Nulli	12	GHT	14.30	13	V	
41	26y	37wks+4days	Multi	11	GHT	14.30	12	V	
42	26y	37wks	Nulli	12	OLIGO	13.30	12.30	V	
43	26y	36wks	Nulli	11	GDM	12.30	11	V	
44	26y	35wks+5days	Nulli	12	OLIGO	15	13.30	V	
45	26y	38wks	Nulli	12	GHT	12.30	10.30	V	
46	26y	37wks	Multi	11	GHT	12.30	10	V	
47	26y	37wks	Multi	11	GHT	12	11.30	V	
48	26y	36wks	Nulli	8	GDM	11.3	–	c	fetal distress
49	26y	37wks	Multi	10	OLIGO	12.30	11	V	
50	26y	37wks	Nulli	12	OLIGO	14	12.30	V	
51	26y	36wks	Nulli	9	GDM	12	10	V	



52	26y	38wks	Multi	10	OLIGO	11	10	V	
53	26y	38wks	Nulli	11	GHT	11.30	10.30	V	
54	27y	37wks	Multi	12	OLIGO	12	11	V	
55	27y	38wks	Multi	12	OLIGO	13	12	V	
56	27y	36wks	Multi	7	GHT	12.30	–	c	msaf
57	27y	37wks	Multi	10	OLIGO	13	9	V	
58	26y	37wks+4days	Multi	11	OLIGO	11	10	V	
59	27y	36wks	Multi	12	GHT	14.30	13.30	V	
60	27y	36wks	Multi	12	GDM	12.30	11	V	
61	27y	37wks	Multi	10	OLIGO	12	11	V	
62	27y	37wks+5days	Multi	11	GHT	11.30	11	V	
63	27y	37wks	Multi	11	GHT	12	11	V	
64	27y	38wks	Multi	12	OLIGO	12.30	11	V	
65	27y	36wks	Multi	10	GDM	13	10.30	V	
66	28y	35wks	Multi	11	GDM	12.30	11	V	
67	27y	38wks	Nulli	12	OLIGO	13	12	V	
68	28y	37wks	Multi	11	OLIGO	13.30	11.30	V	
69	28y	37wks	Multi	10	OLIGO	15	13	V	

70	28y	36wks	Nulli	9	OLIGO	12	11	V	
71	28y	41wks	Multi	9	PDP	13.30	12	V	
72	28y	40wks+5days	Multi	9	PDP	12	9.30	V	
73	28y	42wks	Multi	10	PDP	12	11.30	V	
74	29	37wks	Nulli	7	GHT	15	–	c	Failed induction
75	29	41wks	Nulli	11	PDP	12	11	V	
76	28y	41wks+4days	Multi	12	PDP	12.30	13.30	V	
77	28y	41wks	Multi	10	PDP	13	12.30	V	
78	28y	38wks	Multi	11	GHT	13.30	11.30	V	
79	29y	42wks	Multi	10	PDP	13	11.30	V	
80	29y	42wks	Multi	10	PDP	12.30	11	V	
81	29y	37wks	Nulli	7	GDM	12	11	c	fetal distress
82	29y	36WKS	Multi	11	GDM	12.30	11	V	
83	29y	42wks	Multi	12	PDP	11	10.15	V	
84	29y	35wks+5days	Multi	11	GDM	11.30	10.30	V	
85	29y	40wks+5days	Multi	11	PDP	12	11	V	
86	29y	40wks	Multi	10	PDP	11	10	V	
87	29y	41wks	Nulli	7	PDP	14	–	c	Failed induction

88	29y	41wks	Multi	8	PDP	14	–	c	Failed induction
89	29y	41wks	Multi	11	PDP	13	12.30	V	
90	29y	40wks+5days	Multi	11	PDP	12	10	V	
91	29y	40wks	Multi	12	PDP	14	9	V	
92	30y	41wks	Multi	10	PDP	13	10.30	V	
93	30y	41wks	Multi	10	PDP	13.30	12	V	
94	30y	41wks	Nulli	8	PDP	15	–	c	Failed induction
95	30y	40wks	Multi	12	PDP	12	11	V	
96	30y	40wks+5days	Multi	11	PDP	12.30	11	V	
97	30y	41wks	Multi	10	PDP	14	10.15	V	
98	30y	42wks	Multi	12	PDP	12.30	11	V	
99	30y	41wks	Multi	11	PDP	14	–	c	Fetal distress
100	31y	41wks	Multi	11	PDP	12	9.50	V	